

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

PATENT SPECIFICATION

(11) 1 233 302

DRAWINGS ATTACHED

1 233 302
 (21) Application No. 35319/69 (22) Filed 14 July 1969
 (31) Convention Application No. 768 017 (32) Filed 16 Oct. 1968 in
 (33) United States of America (US)
 (45) Complete Specification published 26 May 1971
 (51) International Classification A 61 b 17/06
 (52) Index at acceptance

A5R 43 45



(54) NEEDLE GUARD

(71) We, BAXTER LABORATORIES INC., a Corporation organised and existing under the laws of the State of Delaware, United States of America, of 6301 Lincoln Avenue, 5 Morton Grove, Illinois 60053, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described 10 in and by the following statement:—

This invention relates to catheter needle guards. In the administration of parenteral fluids, it is now common practice to make a venipuncture with a needle and then thread a sterile plastics catheter into the vein. This catheter is light in weight, flexible and can be taped to the patient's arm to remain in place as long as desired without causing the patient any appreciable discomfort. This so-called 'indwelling' catheter is exemplified by the device disclosed in U.S. Patent 3,335,723.

In such administration procedure, it is virtually impossible to remove the needle unless it contains a slot therein, and many 25 surgeons prefer a needle without a slot. The needle must, therefore, remain around the catheter adjacent the patient's body as long as the catheter remains in place. It is important in such procedure that the needle be 30 immobilized to prevent its puncturing of the patient's skin or cutting of the catheter. It has been customary heretofore to use adhesive tape, gauze padding and the like material to wrap the needle point for this purpose.

Recently, in U.S. Patents 3,323,523 and 3,324,853, various needle protective devices have been suggested for catheter needles of the indwelling type catheter unit. While 40 these devices are useful, they are not without disadvantage insofar as they possess somewhat intricate structures and are difficult to manipulate.

Accordingly, it is an object of the present invention to provide an improved catheter needle guard.

The present invention provides a catheter needle guard comprising a single elongated sleeve for enclosing a needle over a major

part of the periphery of the needle, the sleeve having a longitudinal slot through the thickness of the sleeve, a collar for fastening to a needle hub, and a flexible intermediate section between the sleeve and the collar providing a pivot whereby the sleeve is angularly movable relative to the collar to and from a position substantially co-axial with the collar.

The invention also resides in a catheter needle guard assembly comprising a hub having a catheter needle fixed relative thereto, a passage being defined through the hub and the needle, and a guard comprising a single elongated sleeve having a longitudinal slot through the thickness of the sleeve and a collar connected to the sleeve by a flexible intermediate section providing a pivot, the collar being mounted on the hub and the sleeve being angularly movable by means of said pivot to and from a position substantially co-axial with the collar, the sleeve being snap-engageable over substantially the entire length of the needle in said position.

An embodiment of the invention as at present preferred is described hereafter with reference to the accompanying drawings in which:

Figure 1 is a side elevational view of a catheter needle guard assembly according to the invention;

Figure 2 is a front elevational view of the needle guard part of the assembly shown in Figure 1;

Figure 3 is a sectional view of the needle guard taken along the lines 3—3 of Figure 2;

Figure 4 is a side elevational view showing the needle guard in an operative position.

Referring now to the drawings and particularly Figure 1, the reference numeral 20 is used to indicate generally the hub of a needle having a bore therethrough which can be adapted for fluid communication with any conventional parenteral fluid administration source at extremity 21. The hub 20 has a reduced section or nipple 22. A needle 23 with a pointed distal end 24 for venipuncture is in axial alignment and fluid-tight engagement with the hub 20. A needle

50

55

60

65

70

75

80

85

90

95

guard 25 is provided, the guard having a sleeve 26 with a longitudinal slot 27 through the thickness of the sleeve. The sleeve is snap-engageable over the needle 23 to provide a protective closure therefore. The guard also includes a collar 28 for mounting on the nipple 22 of the hub 20 and a flexible connecting section 29 intermediate collar 28 and the sleeve 26 and defining a pivot for swingable movement of said sleeve 26 between operative and inoperative positions. The sleeve 26 of sufficient size, primarily in thickness and width, to maintain its open or closed position until the application of slight forces such as by manual operation.

The sleeve 26 is constructed of a flexible material with a horseshoe-shaped cross section for convenient snapping over the needle 23 and for retention and immobilization of the needle when in the operative position. The slot 27 preferably has a width at the external perimeter of the sleeve, which is slightly less than the diameter of the needle 23, to facilitate this snapping action and immobilization. The collar 28 is an annulus for convenience in manufacture and for ready mounting on the nipple 22 of the hub 20. Figures 3 and 4, in particular, illustrate the flexibility of the flexible connecting section 29 which is straight in Figure 3 and curved in Figure 4.

In operation of the catheter needle guard unit, the needle guard 25 is in the open position when the needle 23 is used to make a venipuncture in the patient and can be readily snapped into the operative position manually by a finger of the operator after placement of the catheter in the patient and withdrawal of the needle 23. In this operative position, the needle 23 is immobilized to prevent its puncturing of the patient's skin or cutting of the catheter. The catheter needle guard unit can be employed in practice as a sub-component for a complete indwelling catheter device for the administration of parental fluids such as described, for example in U.S. Patent Specification No. 3,335,723. When not in use, the needle guard can be in the closed position to protect the needle 23 from damage, if desired.

A preferred method of making this catheter needle guard unit comprises the heat sealing of an extruded flexible, slotted sleeve 26, having a pre-cut flexible connecting section 29, to a flexible annular collar 28, cut from a piece of tubing, and then solvent sealing said collar 28 to the nipple 22 of the hub 20. For this purpose, the flexible, slotted sleeve 26 and the tubing for collar 28 can be conveniently made from a vinyl plastics such as, for example, plasticized polyvinyl chloride, copolymers of vinyl chloride and vinylidene chloride, copolymers of vinyl chloride and vinyl acetate, or polyvinyl acetate whereas the hub can be con-

veniently made of a relatively more rigid plastics such as for example, polystyrene, copolymers of polystyrene and butadiene, or other rigid solvent-sealable plastics.

It will be apparent that many modifications and variations can be made to the particular embodiments of the invention described hereinbefore. For example, the needle guard 25 can be fastened directly to the needle hub 20 and the needle guard 25 can be fabricated as a single piece, for example, by injection molding of a suitable plastics resin such as polypropylene or polyethylene. The thickness and width of sleeve 26 can vary somewhat, depending in part upon the material of manufacture. Instead of being annular, the collar 28 can be triangular, square, or polygonal in cross-sectional shape, generally depending upon the corresponding shape of the nipple 22 of the hub 20. The collar 28 can be butted directly to the hub 20 instead of along the length of the nipple 22.

WHAT WE CLAIM IS:—

1. A catheter needle guard comprising a single elongated sleeve for enclosing a needle over a major part of the periphery of the needle, the sleeve having a longitudinal slot through the thickness of the sleeve, a collar for fastening to a needle hub, and a flexible intermediate section between the sleeve and the collar providing a pivot whereby the sleeve is angularly movable relative to the collar to and from a position substantially co-axial with the collar.

2. A catheter needle guard according to Claim 1 wherein the sleeve is integrally formed with the intermediate section from plastics material.

3. A catheter needle guard according to Claim 2, wherein the sleeve and the intermediate section are formed from an extrusion having a generally horseshoe-shaped cross-section.

4. A catheter needle guard according to Claim 3 wherein the collar is a flexible annular member.

5. A catheter needle guard constructed substantially as described with reference to and as illustrated in the accompanying drawings.

6. A catheter needle guard assembly comprising a hub having a catheter needle fixed relative thereto, a passage being defined through the hub and the needle, and a guard comprising a single elongated sleeve having a longitudinal slot through the thickness of the sleeve and a collar connected to the sleeve by a flexible intermediate section providing a pivot, the collar being mounted on the hub and the sleeve being angularly movable by means of said pivot to and from a position substantially co-axial with the collar, the sleeve being snap-engageable over substantially the entire length of the needle in said position.

7. A catheter needle guard assembly according to Claim 6, wherein the needle guard is constructed according to any one of Claims 2 to 5. 15

5 8. A catheter needle guard assembly constructed substantially as herein described and illustrated in the accompanying drawings.

9. A method of making a catheter needle guard according to Claim 1, comprising forming an extrusion of plastics material, the extrusion having a generally horseshoe-shaped cross-section, cutting a part of the extrusion to define said intermediate section 20

10.

providing a pivot, the remainder of the extrusion defining said sleeve, and heat sealing the intermediate section to a flexible, annular collar.

10. A method of making a catheter needle guard assembly according to Claim 6 comprising the steps of Claim 9 and then solvent sealing the collar to the hub of the assembly. 20

ERIC POTTER & CLARKSON,
Chartered Patent Agents,
Nottingham.

Printed for Her Majesty's Stationery Office by Burgess & Son (Abingdon), Ltd.—1971.
Published at The Patent Office, 25 Southampton Buildings, London, WC2A 1AY
from which copies may be obtained.

1233302

COMPLETE SPECIFICATION

1 SHEET

*This drawing is a reproduction of
the Original on a reduced scale*

